REMARKS

This submission accompanies an RCE application and is also intended to respond to the Final Office Action of October 24, 2008 issued in connection with the instant application.

Claims 1-55 are in the application.

Claims 1-4, 9, 14, 27 and 29 were rejected as being anticipated by Farrell. Claims 5-7, 10-12, 15-17, 19-21, 24-25, 30-34, 37-39, 41-44, 46-48, 51-52 and 54 were rejected under 35 USC 103(a) as being unpatentable over Farrell in view of Maaskamp. Claims 8, 13, 18, 22, 26, 28,35, 40, 45,49, 53 and 55 were rejected under 35 USC 103(a) as being unpatentable over Farrell in view of Maaskamp et al. and further in view of Kambin.

Farrell was cited as disclosing a trocar (sleeve) 24 with dilators 17, 18 and 19 and with puncturing probe 16 having puncturing tip 14. The Maaskamp reference was cited as showing a transitional conical shape bulging portion as a teaching of improved holding. Maaskamp was also cited as teaching an ultrasonic application. Kambin was cited as showing a hold or grip portion with a slip stopper.

The present invention, as embodied in independent claims 1 and 29, encompasses a trocar system device which is configured to initially puncture its own puncture hole in living tissue. The trocar device is further configured with portions of varying diameter and shape with smooth curved configurations for the device to be comfortably grasped and held for operable use with the palm of one hand of an operator (e.g., page 12, line 22 – page 13, line 19, and page 22, lines 10-26). Claim 1 specifies the following holding configuration (claim 29 has a similar claimed configuration):

"…the trocar comprises a trocar hold portion configured to be held by an operator;

the dilator comprising a dilator insertion portion and a dilator hold portion disposed at the base end of the dilator and configured to be held by the operator;

the dilator hold portion comprising:

a small diameter portion; and a larger diameter portion, the larger diameter portion positioned closer to the dilator insertion portion and having a smooth curved outer surface configured for comfortable gripping and holding of the dilator portion with a palm of one hand of the operator;

the trocar hold portion and the dilator hold portion being interactively configured in a unified body, when the trocar is detachably engaged with the dilator, such **that the operator is able to grasp and hold both the trocar hold portion and the dilator hold portion with the palm of one hand** for one handed puncturing and dilating operation of the trocar system…"

The palm of the hand is capable of exerting forces with simple wrist movement for both perforation and dilation without full arm movement and fatiguing the arm of an operator. This is an important feature for surgical procedures in order to provide requisite force for operations such as puncturing (with minimal trauma) while minimizing effort and fatigue. This feature is particularly applicable with procedures requiring multiple trocar placements.

In response to the Examiner's rejections it is submitted that Farrell's "Percutaneous Femoral Bypass System" is a device which is wire guided through a vein up into the inferior vena cava toward the heart (col. 3, lines 49-52) and is utilized (as dictated by the specific use) with a single dilator device placement. The Maaskamp device is constructed and designed for phaco-emulsification (i.e. ultrasonic emulsification of eye cataracts). Both of the devices of Farrell and Maaskamp are accordingly designed for manipulation with fingers only (though Maaskamp has no manipulation details at all) Farrell shows a threading manipulation utilizing the fingers of both hands of the operator.

There is no disclosure of the Farrell device being controlled by a palm of one hand, as presently claimed, or even any operable utility of providing it with a palm grip for the requisite placement and vein threading. The Maaskamp reference of a device used in eye surgery is certainly not a disclosure of a palm grip manipulated device with enhanced force exertion, as a teaching for modification of the Farrell device. The Maaskamp structure having a conical shape and bulging portions with varying diameters is unrelated to any palm gripping structure but simply a device with artifacts of physical structure (one does not utilize a device in close proximity to an eye with a palm held manipulated device).

Independent claims 1 and 29 have been amended to specifically structurally relate the configuration of the trocar system device being claimed to an operator's manipulative use with a palm of a single hand. Neither Farrell nor Maaskamp disclose, teach or even remotely suggest such use. Maaskamp does not even describe any manipulative use (even with fingers) at all. In fact Maaskamp describes sleeve 20 as being inserted into the eye and one skilled in the art would not even consider conical section 24 adjacent sleeve 20 as being designed for even any finger manipulation (and certainly not a palm) in such close proximity to an eye. There can be no combination of teachings as suggested by the Examiner when there is no teaching in the first instance (Maaskamp's device structure is unrelated to manipulation features).

There is thus no anticipation of claims 1 and 29 by Farrell, which does not disclose, teach or even suggest a device structurally conformed to manipulation by the palm of one hand. Furthermore the Maaskamp reference cannot be validly combined with the Farrell teachings to provide the present claims 1 and 29 (and claims 2-28 and 30-55 dependent thereon).

In addition to the above, it is further submitted that the Examiner's rejection (both based on anticipation and unpatentability) is based on the Examiner's perception that tip 14 of dilator sleeve 16 of the Farrell reference is a tip which is capable of making a puncture hole in living tissue. But in fact, Farrell's detailed disclosure actually contradicts the that this reference teaches or suggests a "tip configured for being capable of making a puncture hole in living tissue".

Initially, it is submitted that there is no mention whatsoever by Farrell of the tip 14 of dilator sleeve 16 making any puncture hole. Secondly, despite the fact that the Examiner purports to illustrate the existence of a sharp tip (at pages 4, 7, 8, 12, 14, 20, 21, 23, 24, 25, 26 of the Final Rejection), in fact the prior art text, does not explain how tip 14 is a "puncturing" tip or that it can be cut at an acute angle to facilitate puncturing.. Thus, the prior art Farrell reference does not provide any basis for the Examiner's modifications or assumption that tip 14 is a puncturing tip.

Element 16 with tip 14, of the Farrell device, is a dilator or dilator sleeve (e.g., col. 2, line 47 and col. 3, lines 57-59) and, as a sleeve, by definition, is hollow throughout its entire length. As shown in Figures 3, 9 and 10 of Farrell, dilator sleeve 16 has a front aperture (i.e., through-tip 14) to allow sleeve 16 to pass over guide wire 13. As a result, tip 14 can be characterized as being "hollow", "perforated" or "apertured" but it **cannot** be characterized as being a puncturing tip since it does not have a sharp point. Though the Examiner has *sua sponte* illustrated how tip 14 could be modified to have a puncturing capability, Farrell specifically teaches how this would be unnecessary since a hypodermic needle 10 is used to puncture the living tissue and position the guide wire 13. The needle is then removed (Figures 6-7B). Tip 14 does not puncture anything and would not be configured with a point to unnecessarily do so. The Farrell dilators all have circular front openings, as more clearly seen in the figures showing the other dilator tips 14', 14'' and 14''' (Figures 1B-1D). Smaller tip 14 perforce has a similar circular opening, in conformity with the other structures, to permit wire 13 to pass into dilator 16 and to prevent tissue tearing. A circular opening cannot however make a puncture hole unless provided with a circular knife edge like a cork borer. Farrell however specifically does not want the dilators to tear any tissue, which would occur if tip 14 of dilator 16 would have any sharp edge or puncturing configuration,

"The **dilator sleeves have smoothly tapered tips** such that the perforation can be gradually enlarged without risk of tearing of the tissue." (Farrell, at col. 1, lines 42-45). This non-tearing requirement also includes the structure of dilator 16 and tip 14. The Examiner's illustrated modifications, with formation of sharp edges, and sharp tip is directly contrary to Farrell's expressed requirement.

The Examiner has responded to Applicant's prior arguments, which were made along the above lines, with several inexplicable responses. In response to Applicant's argument that Farrell does not teach "a hole puncturing probe", the Examiner states that Farrell describes "creating a small perforation or "puncture hole" using a needle and dilating the hole gradually without the risk of tearing the tissue" with support at column 1, lines 42-47. If the Examiner means that the needle is the "probe" as in the present claims, this is clearly refuted by the plain language of the cited full paragraph section (column 1, lines 36-59):

> The present invention, in one aspect, accordingly provides such a system comprising of a series of **dilator sleeves** of gradually increasing internal and external diameters, which can be **progressively inserted over a wire that has been placed into the body within a needle by which an initial, small perforation is made**. The **dilator sleeves have smoothly tapered tips** such that the perforation can be gradually enlarged without risk of tearing of the tissue. The sleeves are flexible and once a perforation of the desired size has been made, a sheath can be placed over them; alternatively the sheath can be mounted around the outer sleeve prior to insertion. The innermost sleeve is provided with a shoulder remote from its tip and each progressively larger sleeve has an inwardly directed flange engageable with the shoulder so that removal of the innermost sleeve naturally results in removal of the whole series of sleeves in one movement. Subsequently a cannula having an external diameter corresponding to the internal diameter of the sheath and having its own obturator may be threaded through the sheath over the wire and the cannula eventually coupled to whatever equipment is appropriate to the support process, for example a heart lung machine.

A needle is never interactively related to the dilator sleeves of Farrell as part of the dilator sleeve system nor is the puncturing needle a probe, as required by the present claims. Independent claims 1 and 29 require that a series of sleeves are positioned over the puncturing probe, with the tip end of the probe projecting from the tip end of a sheath. This is not disclosed or possible with the needle shown by Farrell which is used to make the puncture hole.

Claim 1 of Farrell clearly describes Farrell's system with the inserting of a hypodermic needle, threading of a guide wire through the needle, **removal of the needle from the guide wire**, sliding of a dilator sleeve along the guide wire until the sleeve is inserted, etc. The needle

is removed before any of the dilator sleeves (including dilator sleeve 16 with tip 14) are placed. The needle cannot be construed as a probe used with dilators. There can accordingly be no anticipation by the Farrell reference for another reason.

The Examiner has made an inexplicable statement that the characterization of the probe as having a tip end configured for forming a puncture hole in living tissue is functional and a capability of an intended use and "they do not impose any structural limitations on the claims distinguishable over "a tip end configured for forming a puncture hole in [[a]] living tissue" which is capable of being used as claimed if one desires to do so." This is not a basis for maintaining a rejection based on anticipation since the reference device (without a needle which constitutes no part of the device) cannot form a puncture hole whether one desires to do so or not. A functional limitation must be evaluated and considered just like any other limitation (MPEP 2173.05(g). Furthermore, the language of a "tip end configured for forming a puncture hole in living tissue" must be read broadly as also encompassing a tip end which is structurally configured for being capable of making a puncture hole and not just an intended use.

In fact, the term "configured" is a structural limitation in that it defines a structure for a particular use. In the present instance the probe is structurally made or configured to be able to effect a puncture hole i.e., to form a puncture hole. The word "configured" as a verb has the following definition (copy of on-line definition attached):

tr.v. con·fig·ured, con·fig·ur·ing, con·fig·ures

To design, arrange, set up, or shape with a view to specific applications or uses…

Clearly, the probe structure is structurally designed, arranged, set up or shaped to perform a perforation function. This is a valid structural limitation and is not a functional intended use which can be ignored as the Examiner has done.

Though not necessary, independent claims 1 and 29 have been amended to specify the understood configuration necessary to effect puncture with the language of an elongated probe including, "…a tip end configured to be capable of making a puncture hole in living tissue…". The Farrell tip 14 is not capable of making a puncture hole and would not be modified to make a puncture hole. Accordingly, the Farrell reference neither anticipates the present claims nor renders them obvious even in combination with the other cited references. Claims 1 and 29 are patentable over all of the cited prior art, whether alone or in combination and claims 2-28 and

30-55 dependent thereon are similarly patentable for at least the reasons given with respect to claims 1 and 29.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended and pass this case to issue.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE UNITED STATES PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON JANUARY 15, 2009

Respectfully submitted,

MAX MOSKOWITZ
Registration No.: 30,576
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700